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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,472	EINAT ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 and 13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to the Amendment received on January 21, 2005.

Preliminary Remark

The Office acknowledges the addition of claims 18-22 in the Amendment received on January 21, 2005.

Claim Rejections - 35 USC § 112

The rejection of claims 9 and 13-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on July 22, 2004 is withdrawn in view of the Amendment received on January 21, 2005.

Rejection - Maintained

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 9 and 13-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, made in the Office Action mailed on July 22, 2004 is maintained for the reasons of record.

Claims 18-22 are rejected as being necessitated by Amendment, by way of their new addition, but as their basis for rejection is identical to the issues involving the above claims, are included herein.

Applicants' arguments and the Declaration received on January 21, 2005 have been fully considered but they are not found persuasive for the following reasons.

Applicants' arguments are addressed in the same order they were presented.

In supporting the Applicants' position, Applicants rely on the Written Description Guideline, example 14. Applicants contend that the instant situation is analogous to example 14.

This argument is not found persuasive for the following reasons.

Example 14 recites the below claim:

A protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 and catalyze the reaction of A→B.

The guideline concludes that this claim meets the written description requirement although a single species of protein consisting of SEQ ID NO: 3 because both embodiments embraced by this claim – a) a protein having SEQ ID NO: 3; and b) a protein at least 95% identical to SEQ ID NO: 3 – ***had to have*** the functional limitation of catalyzing the reaction A→B. The guideline states that since the variants embraced by the claim, that is, variants having the requisite homology (via substitutions, deletions, insertions, and additions), ***must*** have the recited catalytic function, one of skill in the art would readily recognize that ***any*** variant having at least 95% homology to SEQ ID NO: 3 ***not*** having this activity would be excluded from the claim. In turn, one of skill in the art would thus recognize that Applicants were in possession of the all variants of requisite homology having the specifically recited catalytic activity.

The instant situation is different, however.

Claim 13 is drawn not only to an isolated polypeptide, activity is unknown, but a polypeptide of unknown function that is encoded by a full-length cDNA which is: **a)** at last 85%

homologous to SEQ ID NO: 3; or **b)** that hybridizes to SEQ ID NO: 3 or that hybridizes to a polynucleotide that is 85% identical to SEQ ID NO: 3, the hybridization conditions of which are recited as being stringent; or **c)** any variant of a) or b) having at least 90% identity thereto; or **d)** a functional derivative of a), b), or c).

To clearly delineate the vastness of the claimed scope, each embodiment embraced by embodiments a)-d) are listed below:

Embodiment a):

I) a protein that is encoded by a polynucleotide that is at least 85% homologous to SEQ ID NO: 3;

Embodiment b):

I) a protein that is encoded by a polynucleotide that hybridizes to SEQ ID NO: 3 under stringent conditions; and

II) a protein that is encoded by a polynucleotide that hybridizes to a polynucleotide that is at least 85% homologous to SEQ ID NO: 3;

Embodiment c):

I) a protein that is at least 90% homologous to a protein that is encoded by a polynucleotide that is at least 85% homologous to SEQ ID NO: 3;

II) a protein that is at least 90% homologous to a protein that is encoded by a polynucleotide that hybridizes to SEQ ID NO: 3 under stringent conditions; and

III) a protein that is at least 90% homologous to a protein that is encoded by a polynucleotide that hybridizes to a polynucleotide that is 85% homologous to SEQ ID NO: 3;

Embodiment d):

I) a functional derivative of embodiments a)-c)

The instant specification discloses a single species, a polynucleotide of SEQ ID NO: 3 encoding a polypeptide of SEQ ID NO: 4. The instant specification does not describe any function associated with the protein encoded by the polynucleotide of SEQ ID NO: 3, other than the fact that the mRNA is overexpressed. The specification does not disclose any variants of SEQ ID NO: 3 nor disclose any examples that describes that a hybridization assay using the SEQ ID NO: 3 was performed under stringent conditions. Applicants' Declaration received on January 21, 2005 demonstrates that polyclonal antibodies were generated against a mouse injected with a fragment of polypeptide encoded by SEQ ID NO: 3 (page 2 of the Declaration, item 3) and that this polyclonal antibodies were employed to detect the expression of protein encoded by SEQ ID NO: 3 (Experiment B). The Declaration discloses no other species of the polypeptide.

Preliminarily, pertaining to the Embodiment d), neither the instant specification nor the Declaration relays to a skilled artisan what the function of the claimed polypeptide is. Absent what the function of such peptide is, one skilled in the art would not recognize that Applicants were in possession of a functional variant of a protein encoded by SEQ ID NO: 3 whose function is not known, and most certainly not recognize that Applicants were in possession of a variant form of the protein encoded by any of the embodiments discussed in Embodiments a), b), and c).

It is noted that the claims are limited by the recitation that all polypeptide and all its "variant" forms (embodiments) be naturally occurring in neural cells whose expression is "***modulated***" and ***induce apoptosis*** in human epithelial breast carcinoma MCF-7 cells. However,

the term, "modulated" embraces both up and down regulated (expressed). Clearly, Applicants only have the description of a protein that which is overeexpressed. Additionally, one of skill in the art would readily recognize that the process of apoptosis is not induced by a single polypeptide, but involves cascades of reactions. Therefore, one of skill in the art would not recognize that Applicants were in possession of a functional derivative of the claimed protein and its variant forms whose function has yet to be determined and whose over and under expression induce apoptosis.

With regard to Embodiments a), b), and c), the instant situation is not analogous to Example 14 of the Written Description Guidelines because Applicants have yet to identify the function of the polypeptide encoded by SEQ ID NO: 3 or the protein comprising SEQ ID NO: 4.

This fact is clearly different from the fact pattern of Example 14, which discusses that the variant form of the polypeptide "catalyze" the reaction A→B.

Applicants, at best, identified that the polypeptide is overexpressed in cell lines treated with a hydrogen peroxide solution (Experiment B). Applicants, however, have not identified whether the claimed polypeptide actually "induces" apoptosis. Neither the specification nor the Declaration provides the evidence that would relay to a skilled artisan that the claimed protein induced apoptosis.

Absent such clear functional description of the claimed protein, one skilled in the art would not readily recognize that Applicants were in possession of the genus of polypeptide and its variant forms embraced by the claim, whose expression is modulated in cells inducing apoptosis.

Applicants discuss Example 9 of the Written Description Guidelines, wherein the example contains the claim that reads:

"An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulate adenylate cyclase activity."

Applicants are advised that the fact pattern of the instant specification is different from that which is governs Example 9.

The conclusion of Example 9, was based on the situation where the specification discloses the ***actual experiment***, hybridizing the polynucleotide of SEQ ID NO: 1 under stringent conditions for the isolation of cDNAs that encode proteins that bind to dopamine receptors and stimulate adenylate cyclase activity. The actual hybridizing nucleic acids were identified by experiment, and ***though not sequenced, were expressed*** (to proteins) and ***showed*** that ***they too bound to a dopamine receptor and stimulated adenylate cyclase activity***.

The instant specification does not follow this fact pattern. Neither the instant specification nor the Declaration give any evidence to support that Applicants were in possession of nucleic acids that hybridize to SEQ ID NO: 3 under stringent condition, nor the proteins encoded by such nucleic acids which modulated and induced apoptosis.

Other than the polypeptide encoded by SEQ ID NO: 3 and polypeptide of SEQ ID NO: 4, one skilled in the art would not recognize that Applicants were in possession of a genus of polypeptides embraced by the instant claims.

Finally, it is also noted that the Declaration does not appear to employ the claimed human epithelial breast carcinoma MCF-7 cells as the description provided in Experiment B is vague:

"***A number of different human cancer cell lines*** were treated with 0.5M H2O2 for 24 hours..." (Experiment B, Declaration).

The rejection is maintained therefore.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
4/15/05

YOUNG J. KIM
PATENT EXAMINER

yjk

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/14/05